

Telefax Transmittal
Cover sheetRECEIVED
CENTRAL FAX CENTER

JUN 15 2004

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966
(302) 934-8051

June 15, 2004

4...pages including cover sheet.

PERSON TO:	COMPANY/DEPT TO:	FAX NUMBER:
------------	------------------	-------------

Examiner P. Baskar	USPTO	703-872-9306
	Group Art Unit: 1645	

PERSON FROM:	COMPANY/DEPT FROM:	FAX NUMBER:
--------------	--------------------	-------------

Diane Payne on behalf of William M. Blackstone	Intervet, Millsboro Patent Dept.	302-934-4305
---------------------------------------------------	-------------------------------------	--------------

RE: USSN: 10/034,500
Attorney Docket No.: 0-2000.605 US

Please accept the documents, which follow in the above-identified application. The last two pages, being pages ten and eleven of the below Power Point Presentation were not faxed with the rest of the document due to an equipment malfunction.

35 U.S.C. 112, first paragraph and the Wands Analysis Power Point Presentation pages ten and eleven of the presentation (2 pages)

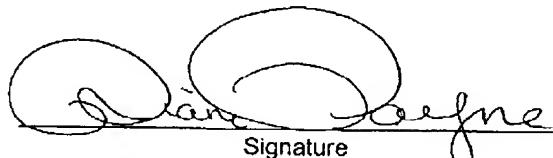
THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED, AND MAY CONTAIN PROPRIETARY INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF YOU ARE NOT THE ADDRESSEE, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, NOTIFY US IMMEDIATELY BY TELEPHONE (COLLECT). THANK YOU.

Certificate of Facsimile Transmission

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on June 15 2004
Date



The image shows a handwritten signature in black ink. The signature consists of the first name 'Diane' and the last name 'Payne' written in a cursive, fluid style. Below the signature, the word 'Signature' is printed in a small, sans-serif font.

Diane Payne
Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

RE: USNN: 10/034,500
Attorney Docket No.: 0-2000.605 US

35 U.S.C. 112, first paragraph and the Wands Analysis Power Point Presentation pages ten and eleven (2 pages)
Certificate of Facsimile Transmission (1 page)

Example D (con't)

- Facts:
 - >Some immunostimulatory oligonucleotide sequences (CpG) are known in the art and are presented in the specification
 - >Specification presents a working example using an art accepted guinea pig model for HSV infection
 - >Art indicates that the guinea pig model, while accurate for studying the development of HSV infection, is not predictive of CpG oligonucleotide sequences that will stimulate an immune response in human individuals

Example D (con't)

- Enablement determination through the Wands factor analysis may turn on less than all factors
- Here, the specification exemplifies an appropriate animal model...on the other hand, there is evidence that this model is not predictive of therapeutic benefit
- Other considerations include role of immune responses stimulated by immunostimulatory oligonucleotide sequences (CpG) resp in prevention as opposed to treatment
- The enablement determination balances all of these considerations.

Intended Use Limitation

- When a compound or composition is limited by a particular use, enablement of that claim should be evaluated based on that limitation.

See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

37

Example C

- Consider the following....

- > A viral vector for use in gene therapy comprising:
a virus comprising a cell binding receptor on the surface thereof and a gene of interest, not normally present in the virus, inserted within the DNA of the virus.
- > A viral vector comprising:
a virus comprising a cell binding receptor on the surface thereof and a therapeutic gene of interest, not normally present in the virus, inserted within the DNA of the virus.
- > A viral vector for delivering a gene of interest to a cell comprising:
a virus comprising a cell binding receptor on the surface thereof and a gene of interest, not normally present in the virus, inserted within the DNA of the virus.

38

Example C (con't)

- Each of the claims on the previous slide contain an intended use:
 - > gene therapy
 - > expression of a therapeutic gene
 - > delivery of a gene of interest into a cell
- The Wands factor analysis continues with determining the scope of the claims.

39

Example D

- A method for preventing a symptom of herpes simplex virus (HSV) infection in an individual who has been exposed to HSV comprising administering a composition comprising an immunostimulatory oligonucleotide sequence in an amount sufficient to prevent a symptom of HSV infection.

40